Claims D 1371-1 WO : 10 March 1997

1. A pharmaceutical aerosol formulation comprising a HFA propellant; a physiologically effective amount of a medicament for inhalation; and a surfactant which is a C_8-C_{16} fatty acid or salt thereof; a bile salt; an alkyl saccharide; or a phospholipid consisting essentially of a single chain phospholipid selected from a lysophosphatidylcholine, a lysophosphatidylglycerol, a lysophosphatidylethanolamine, a lysophosphatidylinositol and a lysophosphatidylserine, or a double chain phospholipid selected from a diacylphosphatidylcholine, a diacylphosphatidylglycerol, a diacylphosphatidylethanolamine, a diacylphosphatidylinositol and a diacylphosphatidylserine.

2. A pharmaceutical aerosol formulation as claimed in claim 1, wherein the surfactant is a C_8-C_{16} fatty acid salt.

3. A pharmaceutical aerosol formulation as claimed in claim 2, wherein the fatty acid salt is selected from the sodium, potassium and lysine salts of caprylate (C_8), caprate (C_{10}), laurate (C_{12}) and myristate (C_{14}).

4. A pharmaceutical aerosol formulation as claimed in claim 1, wherein the surfactant is a trihydroxy bile salt.

5. A pharmaceutical aerosol formulation as claimed in claim 4, wherein the bile salt is selected from the salts of cholic, glycocholic and taurocholic acids.

6. A pharmaceutical aerosol formulation as claimed in claim 5, wherein the bile salt is selected from the sodium and potassium salts of cholic, glycocholic and taurocholic acids.

7. A pharmaceutical aerosol formulation as claimed in claim 6, wherein the bile salt is sodium taurocholate.

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8. A pharmaceutical aerosol formulation as claimed in claim 1, wherein the sufactant is selected from alkyl glucosides and alkyl maltosides.

9. A pharmaceutical aerosol formulation as claimed in claim 8, wherein the surfactant is selected from decyl glucoside and dodecyl maltoside.

10. A pharmaceutical aerosol formulation as claimed in any of claims 1-9, wherein the propellant comprises 1,1,1,2-tetrafluoroethane (P134a), 1,1,1,2,3,3,3-heptafluoropropane (P227) or 1,1-difluoroethane (P152a).

11. A pharmaceutical aerosol formulation as claimed in claim 10, wherein the propellant comprises 1,1,1,2-tetrafluoroethane (P134a) and 1,1,1,2,3,3,3-heptafluoropropane (P227).

12. A pharmaceutical aerosol formulation as claimed in claim 10 or 11, wherein the propellant comprises a density-matched mixture of 1,1,1,2-tetrafluoroethane (P134a) and 1,1,1,2,3,3,3-heptafluoropropane (P227).

13. A pharmaceutical aerosol formulation as claimed in any preceding claim, wherein the medicament is a β2-adrenoreceptor agonist, an anticholinergic bronchodilator,or a glucocorticosteroid.

14. A pharmaceutical aerosol formulation as claimed in claim 13, wherein the medicament is selected from salbutamol, terbutaline, rimiterol, fenoterol, reproterol, adrenaline, pirbuterol, isoprenaline, orciprenaline, bitolterol, salmeterol, formoterol, clenbuterol, procaterol, broxaterol, picumeterol, TA-2005, mabuterol, ipratropium bromide, beclomethasone, fluticasone, budesonide, tipredane, dexamethasone, betamethasone, fluocinolone, triamcinolone acetonide, mometasone, and pharmacologically acceptable esters and salts thereof.

15. A pharmaceutical aerosol formulation as claimed in any of claims 1-12, wherein the medicament is select from anti-allergic medicaments; expectorants; mucolytics;

antihistamines; cyclooxygenase inhibitors; leukotriene synthesis inhibitors; leukotriene antagonists, phospholipase-A2 (PLA2) inhibitors, platelet aggregating factor (PAF) antagonists and prophylactics of asthma; antiarrhythmic medicaments, tranquilisers, cardiac glycosides, hormones, anti-hypertensive medicaments, antidiabetic-antiparasitic- and anticancer- medicaments, sedatives and analgesic medicaments, antibiotics, antirheumatic medicaments, immunotherapies, antifungal and antihypotension medicaments, vaccines, antiviral medicaments, proteins, peptides, vitamins, cell surface receptor blockers, antioxidants, free radical scavengers and organic salts of N,N'-diacetylcystine.

16. A pharmaceutical aerosol formulation as claimed in any preceding claim, including ethanol in an amount of up to 20% by weight of propellant and surfactant.

17. A pharmaceutical aerosol formulation as claimed in any preceding claim, including ethanol in an amount of up to 5% by weight of propellant and surfactant.

18. A pharmaceutical aerosol formulation as claimed in any preceding claim, including other pharmaceutically active agents selected from adjuvants, carriers, flavouring agents, buffers, antioxidants and chemical stabilisers.

19. A pharmaceutical aerosol formulation as claimed in any preceding claim, wherein the surfactant is present in a surfactant : medicament ratio in the range of 1:50 to 1:0.2.

20. A pharmaceutical aerosol formulation as claimed in any preceding claim, wherein the medicament comprises particles having a diameter of 0.01-10 microns.

21. A pharmaceutical aerosol formulation as claimed in claim 20, wherein the medicament comprises particles having a diameter of 0.1-6 microns.

22. A pharmaceutical aerosol formulation as claimed in claim 21, wherein the medicament comprises particles having a diameter of 0.1-5 microns.

23. A pharmaceutical aerosol formulation as claimed in any of claims 20-22, wherein at least 50% of the medicament consists of particles within the said size range.

24. A pharmaceutical aerosol formulation as claimed in any of claims 20-22, wherein at least 60% of the medicament consists of particles within the said size range.

25. A pharmaceutical aerosol formulation as claimed in any of claims 20-22, wherein at least 70% of the medicament consists of particles within the said size range.

26. A pharmaceutical aerosol formulation as claimed in any of claims 20-22, wherein at least 80% of the medicament consists of particles within the said size range.

27. A pharmaceutical aerosol formulation as claimed in any of claims 20-22, wherein at least 90% of the medicament consists of particles within the said size range.

28. A pharmaceutical aerosol formulation as claimed in any preceding claim, wherein the concentration of medicament is 0.1 mg/ml to 25 mg/ml of the formulation.

29. A method for the manufacture of a pharmaceutical aerosol formulation as claimed in any of claims 1-28, comprising the steps of: mixing the medicament and the surfactant and to a vessel at low temperature; adding propellant and optional ethanol; mixing; and adding further propellant and optional ethanol.

30. A pharmaceutical aerosol formulation as claimed in any of claims 1-28, for use in therapy.

31. The use of a pharmaceutical aerosol formulation as claimed in any of claims 1-28 in the manufacture of a medicament for the treatment of diseases via the respiratory tract.

32. A method for the treatment of a patient in need of therapy, comprising administering to said patient a therapeutically effective amount of the pharmaceutical aerosol formulation as claimed in any of claims 1-28.

33. A pharmaceutical aerosol formulation comprising a HFA propellant; a physiologically effective amount of a medicament for inhalation; and a surfactant which is a C_8-C_{16} fatty acid or salt thereof, a bile salt, an alkyl saccharide or a phospholipid, wherein the medicament is selected from formoterol fumarate, budesonide, and ipratropium bromide.